

WE CLAIM:

1. A high fatigue life wire, ribbon, sheet or tubing, comprising:
a core including a binary, nickel-titanium, superelastic alloy in an ingot state having a composition of approximately 54.5 to 57.0 wt.% nickel with a balance of titanium, and trace elements;

the nickel-titanium alloy having an ingot A_f at approximately $-15\text{ }^{\circ}\text{C} \pm 25\text{ }^{\circ}\text{C}$;
and

wherein the core has undergone at least one cold work and full anneal cycle with a final cold work of less than approximately 30 %.

2. The high fatigue life wire, ribbon, sheet or tubing of claim 1, wherein the core has an ultimate tensile strength of \geq approximately 150 ksi in the cold worked condition.

3. The high fatigue life wire, ribbon, sheet or tubing of claim 1, wherein the core has an elongation at failure of \geq approximately 15 % in the cold worked condition.

4. The high fatigue life wire, ribbon, sheet or tubing of claim 1, wherein the core includes a round cross-section.

5. The high fatigue life wire, ribbon, sheet or tubing of claim 1, wherein the core includes a polygonal cross-section.

6. The high fatigue life wire, ribbon, sheet or tubing of claim 1, wherein the core includes a surface that is at least partially polished.

7. The high fatigue life wire, ribbon, sheet or tubing of claim 1, wherein the trace elements in the nickel-titanium alloy includes approximately:

$\leq 0.300\text{ wt.}\%$ (3000 ppm) Fe,

$\leq 0.050\text{ wt.}\%$ (500 ppm) Cu,

$\leq 0.050\text{ wt.}\%$ (500 ppm) O,

$\leq 0.035\text{ wt.}\%$ (350 ppm) C, and

$\leq 0.003\text{ wt.}\%$ (30 ppm) H.

8. The high fatigue life wire, ribbon, sheet or tubing of claim 1, wherein any other single trace element is < 0.1 wt. %.

9. The high fatigue life wire, ribbon, sheet or tubing of claim 1, wherein the core includes an ultimate tensile strength \geq approximately 150 ksi, and elongation at failure \geq approximately 15 %, as measured at a temperature of approximately 23 ± 2 °C and at a strain rate of approximately 0.001/sec.

10. A wire, ribbon, sheet or tubing made from a high fatigue life shape memory material, comprising:

a core including a binary, nickel-titanium, superelastic alloy in an ingot state having a composition of approximately 54.5 to 57.0 wt.% nickel with a balance of titanium, and trace elements of $<$ approximately 0.4 wt.%;

the nickel-titanium alloy having an ingot A_f at approximately -15 °C \pm 25 °C;

wherein the core includes an ultimate tensile strength \geq approximately 150 ksi, and elongation at failure \geq approximately 15 %, as measured at a temperature of approximately 23 ± 2 °C and a strain rate of approximately 0.001/sec.; and

wherein the core has a fatigue life $>$ approximately 20,000 mean cycles to failure under compressive and tensile strain of -0.75 % to +0.75 %.

11. The wire, ribbon, sheet or tubing of claim 10, wherein the core has been cold worked and annealed with a final cold work that is less than approximately 30 %.

12. The wire, ribbon, sheet or tubing of claim 10, wherein the high fatigue life is measured while immersed in a liquid at a temperature above the A_f of a heat treated condition.

13. The wire, ribbon, sheet or tubing of claim 10, wherein the core has a diameter of approximately 0.0050 to 0.0160 inch.

14. The wire, ribbon, sheet or tubing of claim 10, wherein the core has been cold worked through a final cold drawing to reduce a cross-sectional area thereof by less than 30 %.

15. A process for improving the fatigue life of a superelastic metal wire, ribbon, sheet or tubing, comprising:

forming an ingot having a composition of approximately 54.5 to 57.0 wt.% nickel with a balance of titanium and trace elements, with an ingot A_f of approximately $-15\text{ }^{\circ}\text{C} \pm 25\text{ }^{\circ}\text{C}$;

cold working and heat treating the ingot to form a wire, ribbon, sheet or tubing;
and

in a final cold working step, cold working the wire less than approximately 30 %.

16. The process of claim 15, wherein the trace elements in the nickel-titanium alloy ingot includes approximately:

$\leq 0.300\text{ wt.}\%$ (3000 ppm) Fe,

$\leq 0.050\text{ wt.}\%$ (500 ppm) Cu,

$\leq 0.050\text{ wt.}\%$ (500 ppm) O,

$\leq 0.035\text{ wt.}\%$ (350 ppm) C,

$\leq 0.003\text{ wt.}\%$ (30 ppm) H; and

wherein a total amount of trace elements is $< 0.4\text{ wt.}\%$.

17. The process of claim 15, wherein after the final cold working step the process includes mounting the wire, ribbon, sheet or tubing on a fixture and shape setting the wire, ribbon, sheet or tubing at approximately $250 - 600\text{ }^{\circ}\text{C}$ for 1 to 60 minutes.

18. The process of claim 15, wherein the wire, ribbon, sheet or tubing has a fatigue life $>$ approximately 20,000 mean cycles to failure under alternating compressive and tensile strain from -0.75% to $+0.75\%$ in a rotary beam test.

19. The process of claim 15, wherein the process includes electropolishing the wire, ribbon, sheet or tubing.

20. The process of claim 15, wherein the wire, ribbon, sheet or tubing includes an ultimate tensile strength \geq approximately 150 ksi, and elongation at failure \geq approximately 15 %, as measured at a temperature of approximately 23 ± 2 °C, at a strain rate of approximately 0.001/sec.

21. The process of claim 15, wherein the wire, ribbon, sheet or tubing has a fatigue life $>$ approximately 38 million cycles to failure under alternating, loading and unloading forces to produce 80 % to 120 % stretch ratio and corresponding to strain levels of approximately 0.9 % to 1.4 %.

22. A medical device for implantation, comprising:

a sleeve having elastic compliance under expansion forces;

wherein the sleeve includes a binary, nickel-titanium, superelastic alloy in an ingot state having a composition of approximately 54.5 to 57.0 wt.% nickel with a balance of titanium, and trace elements;

wherein the nickel-titanium alloy includes an ingot A_f at approximately -15 °C \pm 25 °C; and

wherein the nickel-titanium alloy includes an ultimate tensile strength of \geq approximately 150 ksi, and elongation at failure is \geq approximately 15 %, as measured at a temperature of approximately 23 ± 2 °C, at a strain rate of approximately 0.001/sec.

23. The medical device of claim 22, wherein the sleeve includes a plurality of wires with a final cold work of less than approximately 30 %.